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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/521,086	03/07/2000	Miladin P. Lazarov	11699-002001	9173

7590 04/09/2004

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EXAMINER

KRUER, KEVIN R

ART UNIT PAPER NUMBER

1773

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/521,086	Applicant(s) LAZAROV ET AL.	
	Examiner Kevin R Kruer	Art Unit 1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-31 is/are pending in the application.
- 4a) Of the above claim(s) 24-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 23, 2004 has been entered.

Election/Restrictions

2. Newly submitted claims 24-31 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 24-31 are drawn to a method of making a product. Said invention was restricted from the product in the Election/Restriction requirement mailed on February 22, 2001. Applicant elected to prosecute the claims drawn to the product in the Response to the Election/Restriction requirement filed on March 26, 2001. MPEP 818.02(a) states that the claims originally acted upon by the Office on their merits determine the invention elected by an applicant in the application, and in any request for continued examination which has been filed in the application.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 24-31 are withdrawn from consideration

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as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 10/19/199. It is noted, however, that applicant has not filed a certified copy of the German application as required by 35 U.S.C. 119(b).

Drawings

4. The drawings filed March 7, 200 are acceptable.

Specification

5. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. ***Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading.*** If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

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- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/25960 (herein referred to as "Lazarov") in view of Guire (US 4,973,493). Herein, US 6,110,204 (the national stage application of Lazarov) is relied upon as an English translation of WO 96/25960.

Lazarov teaches implants for use in the human body. The implants comprise a substrate and a coating that contains chemical compounds of the formula of MN_xO_y , wherein (M) is a metal selected from Group IVA of the periodic table (Ti, Zr, and Hf) (abstract). The formula of MN_xO_y is understood to read on the claimed titanium nitride oxide. The implant can comprise a stent (col 1, line 10).

Lazarov teaches that coagulating inhibiting agents may be applied to the coating (col 5, lines 52+) but does not specifically teach that albumin may be applied. However,

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Guire teaches that surfaces of implantable items have been modified to prevent undesirable protein adhesion by coating the surface with albumin (col 1, lines 57+), such as human albumin (col 10, lines 4+). The albumin coating enhances the item's thromboresistance (i.e. it inhibits coagulation). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply albumin to the surface of the implant taught in Lazarov. The motivation for doing so would have been to improve the thromboresistance of the implant.

The implant taught by Lazarov in view of Guire is understood to read on the claimed implant made by contacting the implant for a limited time with a solution of albumin. The examiner takes this position because the implant taught by Lazarov in view of Guire comprises the same layers comprising the same compositions as the claimed implant. The courts have held that the method of making a product does not patentably distinguish a claimed product from a product taught in the prior art unless it can be shown that the method of making the product inherently results in a materially different product.

8. Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hancock (US 3,755,823) in view of WO 96/25960 (herein referred to as "Lazarov") and Guire (US 4,973,493).

Hancock teaches a coronary stent (abstract) comprised of stainless steel (col 2, line 68).

Hancock does not teach that the coronary stent should be coated with the claimed titanium nitride layer. However, Lazarov teaches an implant coating that

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significantly reduces the activation of blood coagulation accompanied by the formation of thrombi and biofilm (col 2, lines 7+). The coating comprises a material that contains chemical compounds of the formula of MN_xO_y , wherein (M) is a metal selected from group IV A of the periodic table (Ti, Zr, and Hf) (abstract). The formula of MN_xO_y is understood to read on the claimed titanium nitrid oxide. It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the coating taught in Lazarov to the coronary stent taught in Hancock. The motivation for doing so would have been to significantly reduce the activation of blood coagulation accompanied by the formation of thrombi and biofilm.

Lazarov teaches that coagulating inhibiting agents may be applied to the coating (col 5, lines 52+) but does not specifically teach that albumin may be applied. However, Guire teaches that the surfaces of implantable items have been modified to prevent undesirable protein adhesion by coating the surface with albumin (col 1, lines 57+), such as human albumin (col 10, lines 4+). The albumin coating enhances the implant's thromboresistance (i.e. it inhibits coagulation). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply human albumin to the surface of the coronary stent taught by Hancock in view of Lazarov. The motivation for doing so would have been to improve the thromboresistance of the stent.

The implant taught by Hancock in view of Lazarov and Guire is understood to read on the claimed implant made by contacting the implant for a limited time with a solution of albumin. The examiner takes this position because the implant taught by Hancock in view of Lazarov and Guire comprises the same layers comprising the same

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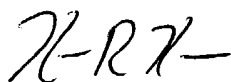
compositions as the claimed implant. The courts have held that the method of making a product does not patentably distinguish a claimed product from a product taught in the prior art unless it can be shown that the method of making the product inherently results in a materially different product.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin R Kruer whose telephone number is 571-272-1510. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Thibodeau can be reached on 571-272-1516. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kevin R. Kruer
Patent Examiner-Art Unit 1773